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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/506,309	09/01/2004	Toru Yamano	3029 US0P	8326
23115 7:	590 08/15/2005		EXAM	INER
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC INTELLECTUAL PROPERTY DEPARTMENT 475 HALF DAY ROAD SUITE 500 LINCOLNSHIRE, IL 60069			FREISTEIN, ANDREW B	
			ART UNIT	PAPER NUMBER
			1626	
			DATE MAILED: 08/15/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/506,309	YAMANO ET AL.					
Office Action Summary	Examiner	Art Unit					
·	Andrew B. Freistein	1626					
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address					
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	86(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).					
Status	• •						
1) Responsive to communication(s) filed on <u>01 September 2004</u> .							
2a) ☐ This action is FINAL . 2b) ☒ This							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under E	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	•						
4)⊠ Claim(s) <u>1-6</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.		•					
8) Claim(s) <u>1-6</u> are subject to restriction and/or ele	ection requirement.						
Application Papers	·						
9) The specification is objected to by the Examine							
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
11) I he oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action of form P1O-152.					
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)⊠ All b)□ Some * c)□ None of: 1.☑ Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
	•						
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date.							
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date		atent Application (PTO-152)					
J.S. Patent and Trademark Office		·					

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DETAILED ACTION

Claims 1-6 are currently pending in the instant application.

Priority

This application is a 371 of PCT/JP03/02563, filed 03/05/2003.

Acknowledgement is made of Applicant's claim for foreign priority under 35 U.S.C. § 119(a)-(d), by Japanese patent application 2002060402 filed on 03/06/2002.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 1-6 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

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"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to numerous and widely divergent variables in the compound of Formula (I), for example: R1, R2, R3, R4, R5, and nitrogen-containing heterocyclic group, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I: Claims 1-6 (in part), drawn to methods for producing compounds of Formula III, wherein R1 is H or an aliphatic hydrocarbon group; R2 is a 5-membered heterocyclic ring with at least one Nitrogen heteroatom; R3 is a hydrocarbon group; R4 is H, or a hydrocarbon group; and R5 is H or a hydrocarbon group, by reacting compounds of Formula I, wherein R1 is H or an aliphatic hydrocarbon group; and R2 is a 5-membered heterocyclic ring with at least one Nitrogen heteroatom, with a compound of Formula II, wherein R3 is a hydrocarbon group; R4 is H or a hydrocarbon group; and R5 is H or a hydrocarbon group.

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Group II: Claims 1-6 (in part), drawn to methods for producing compounds of Formula III, wherein R1 is H or an aliphatic hydrocarbon group; R2 is a 5-membered heterocyclic ring with at least one Nitrogen heteroatom; R3 is a hydrocarbon group; R4 is halogen or a silyl group; and R5 is H or a hydrocarbon group, by reacting compounds of Formula I, wherein R1 is H or an aliphatic hydrocarbon group; and R2 is a 5-membered heterocyclic ring with at least one Nitrogen heteroatom, with a compound of Formula II, wherein R3 is a hydrocarbon group; R4 is halogen or a silyl group; and R5 is H or a hydrocarbon group.

Group III: Claims 1-6 (in part), drawn to methods for producing compounds of Formula III, wherein R1 is H or an aliphatic hydrocarbon group; R2 is a 6-memebered heterocyclic ring with at least one Nitrogen heteroatom; R3 is a hydrocarbon group; R4 is H or a hydrocarbon group; and R5 is H or a hydrocarbon group, by reacting compounds of Formula I, wherein R1 is H or an aliphatic hydrocarbon group; and R2 is a 6-memebered heterocyclic ring with at least one Nitrogen heteroatom, with compounds of Formula II, wherein R3 is a hydrocarbon group; R4 is H or a hydrocarbon group; and R5 is H or a hydrocarbon group.

Group IV: Claims 1-6 (in part), drawn to methods for producing compounds of Formula III, wherein R1 is an aromatic hydrocarbon group; R2 is a 6-membered heterocyclic ring with at least one Nitrogen heteroatom; R3 is a hydrocarbon group; R4 is H or a hydrocarbon group; and R5 is H or a hydrocarbon group, by reacting compounds of Formula I, wherein R1 is an aromatic hydrocarbon group; and R2 is a 6-membered heterocyclic ring with at least one Nitrogen heteroatom, with compounds of

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Formula II, wherein R3 is a hydrocarbon group; R4 is H or a hydrocarbon group; and R5 is H or a hydrocarbon group.

Group V: Claims 1-6 (in part), drawn to methods for producing compounds of Formula III, wherein R1 is an aromatic hydrocarbon group; R2 is a five-membered heterocyclic ring with at least one Nitrogen heteroatom; R3 is a hydrocarbon group; and R4 and R5 are taken together to form a ring, by reacting a compound of Formula I wherein R1 is an aromatic hydrocarbon group; R2 is a five-membered heterocyclic ring with at least one Nitrogen heteroatom, with a compound of Formula II, wherein R3 is a hydrocarbon group; and R4 and R5 are taken together to form a ring.

Group VI: Claims 1-6 (in part) drawn to methods for producing compounds of Formula III, containing compounds not encompassed in Groups I - V. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. As stated above, this is not an exhaustive list, as it would be impossible to produce such a list under the time constraints due to the large volume of subject matter claimed in this application.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Groups I-VI** lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical

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features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-VI** is

CO₂. This technical feature is not a *special* technical feature, because it fails to define a contribution over the prior art (see J.M. Andres, et al. "Synthesis of Chiral Alpha, Alpha-Difluoro-Beta-Hydroxy Esters by Enantioselective Reformatsky Reaction", Synthesis, (1996) pp.1070-1072, No. 9). Therefore, claims 1-6 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a process for the manufacture of a single product.

As a result, the claims lack unity of invention and applicant is required to elect a single invention.

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A telephone call was made to Attorney Mark Chao, Ph.D. on August 1, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew B. Freistein Patent Examiner, AU 1626 Joseph McKane

Supervisory Patent Examiner, AU 1626

Date: August 10, 2005